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Summary of Safety and Effectiveness  
for

**Metagen All Poly Acetabular Cup System**

This safety and effectiveness summary for the Metagen All Poly Acetabular Cup System is provided as required per Section 513(l)(3) of the Food, Drug and Cosmetic Act.

**1. Submitter:**

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- 2. Tradename:** Metagen All Poly Acetabular Cup System  
**Common Name:** Total Hip Prosthesis, Acetabular Component  
**Classification Name:** Acetabular Component of Hip Joint,  
Hip Joint Metal/Polymer, Semi-Constrained Cemented Prosthesis (888.3350)

**3. Predicate or legally marketed devices which are substantially equivalent:**

- Orthomet All-Poly Acetabular Cup (Orthomet)
- Charnley/Elite Plus All Poly Cups (DePuy)
- StelKast All Poly Cup (StelKast)

**4. Description of the device:**

The Metagen All Poly Acetabular Cup System is a family of acetabular components designed for use in total hip arthroplasty, that are manufactured using medical grade biocompatible materials. The basic design and materials are the same as those used in the predicate devices.

**5. Intended Use:**

The Metagen All Poly Acetabular Cup consists of single use devices, intended for cemented replacement of the acetabular portion of the hip joint in primary and revision total hip arthroplasty.

**6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:**

There are no significant differences between the Metagen All Poly Acetabular Cup and the systems currently being marketed, which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, material and intended use.